Exhibit 13

Expert Report of Professor David Cutler

March 25, 2019

6. My curriculum vitae, which provides additional detail about my career and publications is attached as **Appendix III.A**. My billing rate in the matter is $900 per hour. My compensation is not dependent on the outcome of this proceeding. My analysis is ongoing, and I reserve the right to supplement or modify it based on new materials or testimony that may become available to me, including, but not limited to, other expert witness reports that have not been produced prior to the completion of my assignment.

II. Assignment and Summary of Conclusions

7. This litigation, brought by Cuyahoga County and Summit County (collectively referred to herein as the "Bellwether governments" or "Bellwether jurisdictions" or "Bellwether plaintiffs"), alleges among other things that the defendant manufacturers' conduct in "promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin."[3] The governments further allege that the opioid epidemic and the need for increased services, "arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution."[4] In addition, the Bellwether plaintiffs allege "the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies . . . who failed to

[3] In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-OP-45004, Second Amended Complaint, May 18, 2018, ("Cuyahoga Complaint"), ¶19; In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-md-2804, Corrected Second Amended Complaint, May 18, 2018, ("Summit Complaint"), ¶20.

[4] Cuyahoga Complaint, ¶3; Summit Complaint ¶3.

maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls . . . thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market."[5] I refer to these actions collectively as "defendants' misconduct." I also refer to the adverse health, public health, public welfare and criminal justice consequences of the opioid epidemic as "harms."

8. An analysis of damages incurred by the Bellwether jurisdictions due to defendants' misconduct requires an evaluation of the impact of prescription opioid shipments on harms that impose costs on Bellwether jurisdictions. As part of this analysis I also review how shipments of prescription opioids ultimately resulted in harms stemming from illicit opioids. The costs imposed on the Bellwethers from these harms are addressed in the Expert Report of Prof. Thomas McGuire (the "McGuire Report").[6] To be clear, for purposes of this report, the impact of prescription opioid shipments on harms to the Bellwethers includes all of defendants' misconduct I described above, including all defendants who used or endorsed deceptive marketing strategies and all defendants who failed to maintain effective controls over the distribution of prescription opioids.

9. My analysis yields annual estimates of the share of various harms imposed on selected departments in each Bellwether government ("Bellwether divisions") that is attributable to

[5] Cuyahoga Complaint, ¶14, Summit Complaint, ¶14.

[6] Because aspects of analyses presented in the report are related to analysis included in the Expert Report of Professor Jonathan Gruber ("Gruber Report"), the Expert Report of Professor Meredith Rosenthal ("Rosenthal Report") and the Expert Report of Professor Thomas McGuire ("McGuire Report"), the following numbering convention is adopted to identify tables, appendices and back up materials from each report: Materials related to this report are identified with the prefix III (e.g., Table III.1); materials related to the Gruber Report use the prefix I; materials related to the Rosenthal Report use the prefix II; and materials related to the McGuire report use the prefix IV.

defendants' misconduct. The analysis incorporates two alternative estimates of the share of prescription opioid shipments that are attributable to misleading marketing, which are set forth in the Expert Report of Prof. Meredith Rosenthal (the "Rosenthal Report").[7] An alternative version of my analysis reported in Appendix III.J to this report incorporates an estimate of the share of prescription opioids that should have been identified as suspicious by distributors.[8]

10. My assignment in this report thus is to evaluate the following issues identified by counsel and to answer the following questions framed by counsel:

What was the effect of prescription opioid shipments on harms that resulted in county costs?

1) *For each administrative division for which one or more of the Bellwether governments seeks recovery, did the increase of prescription opioid shipments since 1995 contribute to harms that result in costs faced by the relevant divisions?*

2) *What is the size of these effects? For each administrative division, calculate the percentage of harm attributable to prescription opioid shipments in each year 2006-2018 for each of the Bellwether governments.*

3) *For each administrative division for which either Bellwether government seeks recovery, what is the percentage of harm attributable to prescription opioid shipments for which defendants are responsible in each year 2006-2018 for each Bellwether government?*

4) *Provide the economic rationale for your estimates.*

[7] Prof. Rosenthal presents estimates of the share of prescription opioid shipments due to defendants' misconduct using (1) a direct shipments regression method; and (2) an indirect shipments regression method. Section VI of this report incorporates the estimates from the direct regression method. Appendix III.K presents an analysis of the percent of harms due to defendants' misconduct based on the indirect regression method.

[8] I understand certain expert reports related to distributor misconduct are not being disclosed until April 15, 2019. Appendix III.J contains inputs that will also be set forth in reports that will be disclosed that day. As set forth above, I reserve the right to modify this analysis based on filed version of those reports.

23. This approach can be summarized by the multiplication of the three components, as summarized in the following equation:[12]

$$\begin{aligned} &Share\ of\ Harms\ Attributable\ to\ Defendants'\ Misconduct \\ &= \ Share\ of\ Harms\ Attributable\ to\ Opioids \\ &\quad x\ Share\ of\ Opioid\ Harms\ Attributable\ to\ Opioid\ Shipments \\ &\quad x\ Share\ of Opioid\ Shipments\ Due\ to\ Defendants' Misconduct \end{aligned}$$

B. Share of Harms Attributable to Opioids

24. The first step in implementing this framework requires estimating the share of various harms attributable to opioids, including those related to both prescription opioids and illicit opioids. This first step can itself include multiple parts, and for several categories of harm requires estimating (i) the share of harms that are due to drug use in general (including both opioids and non-opioids) and (ii) the share of these drug-related harms that are attributable to opioids. More specifically, for many types of harm the calculation is:

$$\begin{aligned} &Share\ of\ Harms\ Attributable\ to\ Opioids \\ &= \ Share\ of Harms\ Attributable\ to\ Drugs \\ &\quad x\ Share\ of\ Drug\ Harms\ Attributable\ to\ Opioids \end{aligned}$$

In some instances, however, data are available that allow direct estimation of the percentage of harms due to opioids in a single calculation.[13]

25. The data and precise method used to estimate the share of harms attributable to opioid misuse in this first step vary by type of harm and are discussed in more detail below. This

[12] This formulation accurately summarizes the steps of the calculation. As discussed further below, implementation of the approach to develop year-specific estimates involves more complex calculations.

[13] For example, the Cuyahoga Medical Examiner's office provides data directly on opioid-related overdoses.

general approach for estimating the share of harms that are due to opioids has been extensively used in scientific literature for evaluating the costs attributable to the opioid epidemic, including for example in CEA (2017), Florence, et al. (2016), Birnbaum et al. (2011), Hansen et al. (2011), and Birnbaum et al. (2006).[14]

C. Share of Harms Attributable to Opioid Shipments

26. The second step of the analysis requires an estimate of the share of opioid-related harms that is attributable to shipments of prescription opioids, as opposed to opioid-related harms that would have occurred even in the absence of shipments of prescription opioids. For this analysis, opioid-related mortality is used as a proxy for opioid-related harms and the share of opioid-related mortality which is attributable to shipments of prescription opioids is estimated. Two different statistical methods are used in estimating this element of the calculation.

- The first method is based on regression estimates of the relationship between changes over time in opioid mortality across different geographic areas and shipments of prescription opioids in those areas. This regression is used to estimate the elevation in opioid-related mortality due to shipments of prescription opioids. This is referred to as

[14] Council of Economic Advisors. "The Underestimated Cost of the Opioid Crisis." (2017); Florence, Curtis S., Chao Zhou, Feijun Luo, and Likang Xu. "The economic burden of prescription opioid overdose, abuse, and dependence in the United States, 2013." *Medical Care* 54 (2016): 901-906 (Florence et al (2016)); Birnbaum, Howard G., Alan G. White, Matt Schiller, Tracy Waldman, Jody M. Cleveland, and Carl L. Roland. "Societal costs of prescription opioid abuse, dependence, and misuse in the United States." *Pain Medicine* 12 (2011): 657-667 (Birnbaum et al (2011)); Hansen, Ryan N., Gerry Oster, John Edelsberg, George E. Woody, and Sean D. Sullivan. "Economic costs of nonmedical use of prescription opioids." The Clinical Journal of Pain 27 (2011): 194-202 (Hansen et al (2011)); Birnbaum, Howard G., Alan G. White, Jennifer L. Reynolds, Paul E. Greenberg, Mingliang Zhang, Sue Vallow, Jeff R. Schein, Nathaniel P. Katz. "Estimated costs of prescription opioid analgesic abuse in the United States in 2001: a societal perspective." *The Clinical Journal of Pain* 22 (2006): 667-676 (Birnbaum et al (2006)).

the "direct approach" because it specifically seeks to directly model the causal effect of shipments on mortality. As discussed further below, regression models of this type are commonly used in economic analysis.

- The second method is based on a regression analysis of the relationship between opioid mortality across geographic areas and the economic and demographic characteristics of those areas in a "base period" that, in principle, precedes defendants' misconduct alleged in this case. This base period regression is then used to predict opioid mortality rates that would have been expected due to changes in economic and demographic factors in the absence of defendants' misconduct. The resulting difference between actual and "but for" opioid-related mortality yields an alternative estimate of the impact of shipments of prescription opioids on opioid-related mortality. This is referred to as the "indirect approach." As discussed further below, analysis of the impact of economic events using an "indirect" approach of this type is common in economic analysis.

27. The motivation for the choice of and applications of these statistical analyses are discussed in more detail in Section V below. Combining the results of the first two steps of these calculations – the share of harms faced by Bellwether governments attributable to opioids and the share of opioid-related harms attributable to shipments of prescription opioids – yields an estimate of the share of various harms that are attributable to prescription opioid shipments.

D. Share of Opioid Shipments Attributable to Defendants' Misconduct

28. The third step in the analysis is to incorporate estimates of the share of the opioid-related shipments that are attributable to defendants' collective misconduct. If all shipments of opioids were the result of misconduct, then there would be no difference between estimates of the harm attributable to opioid shipments and harm attributable to shipments that resulted from misconduct by defendants. Professor Rosenthal reports year-specific estimates of the extent to which shipments of prescription opioids resulted from defendants' marketing misconduct which indicate that most, but not all, shipments are attributable to defendants' marketing misconduct.

E. Attribution of Harm Across Multiple Responsible Parties

29. The methodology laid out here yields an estimate of the share of various harms in Bellwether jurisdictions that stem from misleading marketing of prescription opioids as calculated in the Rosenthal Report. However, this does not mean that improper marketing is solely responsible for these harms. I have been instructed to assume that all registrants of the CSA including distributors of prescription opioids have legal obligations to maintain effective controls against diversion, including to identify excessive shipments and to prevent such shipments and report them to the appropriate regulatory authorities. The Bellwether complaints claim that defendants' failure to control the supply chain and their "deliberate efforts to evade restriction on opioid distribution" was a contributing factor to the opioid epidemic.[15]

[15] Cuyahoga Complaint, ¶3, Summit Complaint ¶3.

30. Analysis presented in the Gruber Report establishes wide variation in per capita shipments across counties after controlling for demographic differences in population characteristics. This indicates that many shipments were both excessive and were not identified and prevented by CSA registrants, including distributors. This in turn implies that some harms, and thus damages to Bellwether governments, could have been avoided if these defendants had acted properly.

31. The analysis presented here does not attempt to uniquely apportion harm resulting from actions by any individual type of defendant. In some circumstances when multiple parties contribute to the same indivisible harms, it is unlikely that a unique attribution of harm to each contributing party is possible. This report first presents estimates of harm that stem from the elevation in shipments resulting from marketing misconduct. However, as noted, such harms cannot be solely attributable to manufacturers since some harm could have been prevented had all registrants of the CSA, including distributors, met their legal obligations. **Appendix III.J** shows how the framework for estimating harm developed in this report can be applied to estimate harms that could have been avoided in the absence of supply-chain misconduct by CSA registrants including distributors.

IV. Estimation of the Share of Harms Attributable to Opioids

32. This section discusses implementation of the first step of the analysis – estimation of the share of various harms faced by Bellwether governments that are attributable to opioids. The

section describes the key elements of the calculations and the data that underlies these calculations for each of the harms that impose costs on the Bellwether governments.

33. As noted, for most harms, the calculation of the share that is attributable to opioids itself involves two distinct steps: (i) estimation of the percent of harms due to drug use as a whole and (ii) estimation of the percent of drug activity due to opioids. These two components are then multiplied to yield an estimate of the share of harms that are attributable to opioids. A brief description of these calculations is presented below for each of the different categories of harm. The full details of the data and calculations are presented in the **Appendices III.C through III.G** attached to this report.

A. Share of Crime Attributable to Opioids

34. The share of criminal activity attributed to opioids is used to estimate opioid-related costs across Bellwether divisions with responsibilities that include policing, courts and adjudication, and corrections. Therefore, while the general estimation method is the same across these divisions (or types of activities), the data used in the calculation can vary by division and Bellwether depending on activity and data availability. Descriptions of the methodology and data used are provided below, including discussions of differences, when relevant, across divisions and Bellwether governments.[16]

35. To measure the share of crime due to opioids, data are utilized on criminal activity for each Bellwether and crime-related division.[17] These data provide information on the total

[16] As referenced above, this methodology (and many of the data sources used in the estimation) follow the literature of Florence, et al. (2016), Birnbaum et al. (2011), and Birnbaum et al. (2006).

[17] Criminal activity is measured as crime offenses, criminal bookings, or criminal charges depending on the data source listed in Table III.2.

[redacted]

[38] See Chow, Gregory C. "Tests of equality between sets of coefficients in two linear regressions." *Econometrica: Journal of the Econometric Society* 28 (1960): 591-605; Quandt, Richard E. "Tests of the hypothesis that a linear regression system obeys two separate regimes." *Journal of the American statistical Association* 55 (1960): 324-330; Fisher, Franklin M. "Tests of equality between sets of coefficients in two linear regressions: An expository note." *Econometrica: Journal of the Econometric Society* 28 (1970): 361-366; An F-statistic is used in econometrics to test whether the values across two groups differ from each other. The largest F-statistic identifies the month associated with the largest difference in the trends (growth rates) of heroin mortality between the two periods.

[39] Evans et al. (2019) present a similar analysis and reach a similar conclusion.

Source: NCHS Mortality Data

58. Consistent with the events described above, mortality associated with prescription opioids (not involving illicit opioids) also started to decline around the same time as the acceleration of illicit opioid deaths. A similar analysis establishes that the long-term trend of increasing prescription opioid mortality was reversed around the same time and that the best estimate of this shift was December 2010. **Figure III.3** reports the prescription opioid mortality rates and the regression estimate of the trends before and after the best estimate of the date of the shift in the rate.

Source: NCHS Mortality Data

59. The shift in the nature of the opioid crisis does not mean that historical levels of shipments are irrelevant to understanding the emergence of heroin opioid mortality. To the contrary, available data demonstrate that the increase in heroin-related mortality was greatest in counties with high historical levels of shipments and lower in areas with relatively lower levels of historical shipments. This pattern is consistent with the view that (i) historical shipments (and the consequent opioid dependence) played an important role in contributing to the demand for illicit opioids after 2010, and (ii) factors such as reduced shipments of prescription opioids and development of abuse deterrent formulations resulted in an increased demand for illicit opioids in all areas.

60. These effects are clearly demonstrated in the results of performing an additional test on annual heroin mortality data from two groups of counties: those with shipments of prescription opioids from 1997-2010 within the top 25% of counties ("high shipment counties") and those with shipments in the bottom 25% of counties ("low shipment counties").[40] **Figure III.4** summarizes this test, which establishes that while both areas have clear shifts in the trend in heroin mortality after 2010, the acceleration in heroin mortality is significantly larger in the high shipment counties. The difference in the change in slope and level is statistically significant.

Source: NCHS Mortality Data and ARCOS

[40] County-specific mortality data are only available on an annual basis. National data are available on a monthly basis.

61. This finding is consistent with the economic literature that has studied the transition from prescription to illicit opioids in the post-2010 time period. For example, Evans et al. (2019) evaluated a similar set of statistical tests using state-level mortality data and found evidence of substitution from prescription opioids to heroin. They conclude that "there appears to have been one-for-one substitution of heroin deaths for opioid deaths."[41] Similarly, Alpert et al. 2018 analyzed prescription shipments and mortality data in a panel data context and concluded that areas with high levels of abuse of OxyContin are associated with large increases in heroin mortality following 2010.[42] The same authors have now extended the work to study the growth in infections of hepatitis C since 2010 and conclude that areas with higher levels of OxyContin abuse have seen much larger growth in the virus, which is frequently contracted through intravenous drug use.[43]

62. Moreover, a number of epidemiological studies have established that much of the increase in the use of illicit opioids after 2010 was the result of addictions resulting from prior use of prescription opioids. Several of the studies are reviewed in the Gruber Report, so they are only briefly noted here.[44] Key studies establish that:

- A survey of heroin patients in drug treatment centers that reported initiating use in the 2000s established that 75 percent initiated opioid use with prescription opioids.

[41] Evans et al. (2019), at p. 2.
[42] Alpert, Abby, David Powell and Rosalie Liccardo Pacula. "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids." *American Economic Journal: Economic Policy* 10 (2018): 1-35, p. 4.
[43] Powell, David, Abby Alpert, and Rosalie L. Pacula. "A Transitioning Epidemic: How the Opioid Crisis is Driving the Rise in Hepatitis C." *Health Affairs* 38 no. 2 (2019): 287-294.
[44] I understand that the Expert Report of Dr. Katherine Keyes also reviews related studies.

Among respondents that began using opioids in the 1980s, the comparable figure was 30 percent.[45]

- Analysis of NSDUH survey data established that among respondents that reported using both heroin and prescription opioids (for non-medical use), the share that reported initially using prescription opioids was 83 percent in 2008-10.[46]

63. These studies and the analyses presented above in **Figures III.2** through **III.4** demonstrate that the increase in deaths due to illicit opioid use is closely related to the growth in demand for illicit drugs after 2010. Since the increased demand for illicit opioids would not have occurred absent defendants' misconduct resulting in increased shipments of prescription opioids and CSA registrants' failure to identify excessive shipments, the resulting harm relating to illicit opioids is appropriately attributable to defendants' actions. Simply stated, the available data indicate that in the absence of shipments of prescription opioids, the post-2010 increase in mortality due to heroin and fentanyl would not have occurred. This is also confirmed by the analysis below.

B. Statistical Models of the Impact of Prescription Opioid Shipments on Mortality

64. Statistical analysis of the impact of shipments of prescription opioids on mortality must recognize both the dramatic change in nature of the opioid crisis after 2010 discussed above, as well as the limitations of available data. This section motivates and outlines statistical

[45] Cicero, Theodore J., Matthew S. Ellis, Hilary L. Surratt, and Steven P. Kurtz. "The changing face of heroin use in the United States: A retrospective analysis of the past 50 years." *JAMA Psychiatry* 71 (2014): 821-826, p. 823.
[46] Jones, Christopher M. "Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010." *Drug and Alcohol Dependence* 132 (2013): 95-100, p. 97.

frameworks for estimating the impact of shipments of prescription opioids on opioid-related mortality that are informed by the changing nature of the crisis and other factors.

1. Framework 1: Direct Estimation of the Impact of Shipments of Prescription Opioids on Mortality

65. The "direct estimation" framework uses regression analysis to estimate the relationship between the increase in opioid-related mortality in a geographic area and per capita shipments of prescription opioids to that geographic area. The analysis yields estimates of the magnitude and statistical significance of that relationship. Regression analysis is a reliable and commonly used method to analyze the relationship between economic variables. It is widely used in the fields of economics and other social sciences and in expert analysis for the purposes of litigation.[47] Examples of regression analyses similar to the "direct estimation" approach are discussed further below.

a. Regression Specification

66. The regression framework used to estimate the relationship between opioid shipments to an area and changes in opioid-related mortality can be expressed as the following:

$$\begin{pmatrix} Change\ in\ opioid\ - \\ related\ mortality \end{pmatrix}_i = \beta_1 \begin{pmatrix} Opioid\ shipments \\ per\ capita \end{pmatrix}_i + X_i\beta + \varepsilon_i$$

The analysis evaluates the relationship between change in mortality between two periods of time (e.g. between 1995 and 2010) in a county (*i*) to per capita shipments to that county, as well as to various economic and demographic characteristics of the county (X_i). The

[47] See, for example: Daniel L. Rubinfeld, "Reference Manual on Multiple Regression," *Reference Manual on Scientific Evidence* 3rd. Ed. Federal Judicial Center, National Academies Press (2011): 303-358.

relationship between the various explanatory variables and changes in mortality (β) are estimated in the regression model and ε_i reflects the change in mortality that is not explained by the regression. The key coefficient is β_1, which describes the magnitude of the relationship between prescription opioid shipments and opioid mortality, and for which we can also determine statistical significance. The regression model can then be used to project the change in mortality that would have been observed in the typical area if, for example, there had been fewer or no shipments of prescription opioids. These estimates, in turn, can be combined with estimates of the share of shipments that is attributable to defendants' misconduct described in the Rosenthal Report to yield an estimate of the share of opioid-related harms that can be attributed to prescription opioid shipments resulting from defendants' misconduct.

67. The regression analysis relates the changes in mortality in a county to the average level of per capita shipments to that county through 2010. As discussed above, mortality due to illicit opioids increased significantly after 2010. There continued to be deaths from "licit" opioids (prescription opioids other than fentanyl but including methadone) after 2010, although the rate of such deaths started to fall. As discussed further below, the estimated relationship between shipments and mortality through 2010 can be used to estimate the share of mortality from licit opioids that can be attributed to shipments of prescription opioids after 2010.

b. Limitations of Direct Model

68. The direct regression specification has two limitations that are discussed below. These limitations imply that (1) it is inappropriate to use a direct regression method to measure the effect of prescription opioids on opioid mortality after 2010; and (2) a direct regression method

likely understates the relationship between prescription opioid shipments on opioid mortality even for the period prior to 2010.

i. The Direct Regression Model is Not Suitable to Estimate the Relationship between Prescription Opioid Shipments and Opioid Mortality After 2010

69. As shown above, after 2010 declines in shipments of prescription opioids generated increased demand for illicit opioids and rapid increases in deaths due to illicit opioids. These events fundamentally altered the relationship between shipments of prescription opioids to an area and opioid-related mortality.

70. Specifically, the increase in deaths due to illicit opioid use after 2010 depends not just on the increase in demand for illicit opioids due to the decline in supply of prescription opioids, but also on the supply of illicit opioids in an area. For example, if two areas have the same increase in the demand for illicit opioids (due perhaps to having had the same level of historical shipments), deaths due to illicit opioid use would be likely to increase more in the area with greater supply of illicit opioids. Thus, the relationship between shipments and opioid-related mortality in the post-2010 period is likely to be weaker than the relationship in the earlier period.

71. The "supply side" of the illicit drug marketplace depends on factors such as the presence and sophistication of networks of drug dealers, their ability to increase supply of illegal opioids in response to an increase in demand, and the type of heroin which was being supplied to an area. Supply conditions in the illicit marketplace cannot be directly observed, due in part to the illegal nature of this activity. Nor can consumption of illicit opioids be observed – for the same

reason. Thus, some of the factors that contributed to the increase in mortality from illicit opioids after 2010 cannot be incorporated into a statistical analysis like that which is indicated for the analysis through 2010. However, the presence and sophistication of drug networks is partially a result of opioid shipments prior to 2010, as they created 'thicker markets' for illegal products.[48] This informs Framework 2, the methodology that is employed for the post-2010 period, which is described in detail further below.

ii. Impact of Mismeasurement on the Estimate of the Relationship Between Shipments and Mortality

72. Even limiting the direct analysis to the period up to and including 2010 would still understate the true impact of shipments on opioid mortality and thus is appropriately considered a "lower bound" estimate of this relationship. As explained further below, the estimation of the direct analysis establishes that the growth in opioid-related mortality through 2010 in an area is strongly related to shipments of prescription opioids to the area, and this relationship is statistically significant. However, as a general matter, the direct approach will understate the magnitude of the true relationship between prescription opioids and mortality.

73. To understand why, it is important to recognize that the ideal analysis would relate mortality to consumption of prescription opioids. While shipments to an area may be highly correlated with consumption, the two are not the same. In particular, some shipments to an area are transported and sold to people living in other areas. For example, Florida had one of the highest per capita shipments of prescription opioids in the late 2000s. However, it is widely

[48] See discussion of thicker markets in the Gruber Report and in Vulkan, Nir, Alvin E. Roth, and Zvika Neeman, eds. *The Handbook of Market Design*. Oxford: Oxford University Press, 2013, p. 3.

recognized that many prescriptions written by Florida physicians were diverted to other areas, including Ohio, Kentucky, West Virginia and other nearby states. This flow of prescription opioids was known as the "Oxy Express" and is discussed at length in *Dreamland* and elsewhere, including in the Evans et al. (2019) study referenced above.[49] Some of the defendants in this litigation have also acknowledged the existence of the "Oxy Express", including specifically to Ohio.[50] As a result, consumption per capita is likely to have been higher than shipments per capita in Ohio, but lower than shipments per capita in Florida.

74. However, data on consumption in an area are not available, so data on shipments to the area are used as a proxy for consumption. Standard econometrics texts recognize that measurement error of this type will result in regression estimates that underestimate the magnitude of the true underlying economic relationships.[51] Here, the estimated relationship between shipments and mortality will understate the relationship between consumption and mortality.

75. Moreover, available data on shipments are defined on the basis of morphine equivalents (MMEs) per capita. While this provides a comprehensive measure of shipments of prescription opioids measured on an "apples to apples" basis, it does not permit the evaluation

[49] Quinones, Sam. *Dreamland: the true tale of America's opiate epidemic*. New York, NY: Bloomsbury Press, 2016, pp. 241-246. This phenomenon is also discussed in Evans et al. (2019) at p. 11. See also, Alan Johnson, "Florida urged to keep tracking painkillers; Program essential to curb 'pill mills,' Ohio's Sen. Brown tells Gov. Scott," *The Columbus Dispatch*, March 5, 2011; Amy Hollyfield, "Gov. Rick Scott signs legislation to crack down on pill mills," *St. Petersburg Times*, June 3, 2011; Lizette Alvarez, "Florida Shutting 'Pill Mill' Clinics," *The New York Times,* September 1, 2011. See also discussion in the Gruber Report.

[50] See, e.g., January 15, 2019 Deposition Transcript of Karen Harper, Director of Controlled Substance Compliance, Mallinckrodt, at pp. 91-92.

[51] See, for example, Wooldridge, Jeffrey M. *Econometric analysis of cross section and panel data*. Cambridge, Massachusetts: MIT press, 2010, pp. 80-81 for a discussion of errors in variables.

of prescription-level characteristics that also may affect misuse and mortality. For example, available data do not permit analysis of the impact on mortality of factors such the average number of days for which prescriptions are written, whether the prescribed drug was long acting or extended release formula, or the average dosage prescribed per day. Each of these is likely to affect the relationship between shipments and addiction, crime, mortality, and other outcomes. For the same reason just discussed above, this type of mismeasurement problem would also be expected to lead to an underestimate of the true relationship between consumption and mortality.

2. Framework 2: Indirect Approach to Estimating the Impact of Shipments on Opioid Mortality

76. An indirect regression method is an alternative way to estimate the impact of defendants' actions on mortality.[52] This method is based on a regression analysis of the relationship between opioid mortality in a given geographic area and the economic and demographic characteristics of an area in a period that (arguably) precedes increases in prescription opioid shipments due to the defendants' misconduct. This regression is then used to predict the opioid mortality rates that would have been expected given changes in economic and demographic factors in the absence of the increase in prescription opioid shipments due to the defendants' misconduct. The gap between actual mortality and this "but for" mortality yields an alternative estimate of the impact on mortality from the increase in shipments of prescription opioids above the baseline level of shipments predicted by the economic and demographic characteristics in that area.

[52] See discussion below on the general applicability and reliability of indirect regression methods in economics.

77. The regression equation used in the indirect approach can be expressed:

$$Opioid\ Mortality\ Rate_i^{Pre} = X_i^{Pre}\,\beta + \varepsilon_i$$

The analysis evaluates the relationship between mortality in the "pre-period" (before defendants' alleged misconduct and resulting impact on shipments) in county *i* and various economic and demographic characteristics of the county (X_i). The relationships between the various explanatory variables and pre-period mortality (β) are estimated in the regression model where ε_i reflects the portion of the county-level mortality in the "pre-period" that is not explained by the regression. As discussed further below, the regression analysis accounts for a wide variety of factors that potentially affect opioid mortality including the demographic characteristics of the population and various measures of economic opportunity.

78. Based on these estimates of the relationship between the economic and demographic characteristics of counties and opioid mortality in the "pre-period," the model can then generate estimates for "but for" opioid mortality in the "post-period" by predicting mortality using changes in the X_i variables over time. As discussed further immediately below, two versions of the indirect model are used in the analysis:

- First, an indirect model is used to estimate the level of deaths due to illicit opioid use that would have been observed in the absence of the increase in demand for illicit opioids after 2010. This version of the indirect model is used in conjunction with the direct model for 2010 and earlier years to estimate the harms due to defendants' misconduct after 2010.

Appendix III.J: Framework for Estimating Harms Due to Distributor Misconduct

1. As the Bellwether plaintiffs have alleged, the opioid epidemic and the need for increased services, "arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution."[1] While the defendants' misleading marketing contributed to the opioid epidemic, "the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies . . . who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls . . . thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market."[2]

2. Tables III.13 and III.14 report the share of harms due to defendants' misconduct that are based on estimates of the share of prescription opioid shipments attributable to misleading marketing reported by Prof. Rosenthal. While this estimate may reflect the harm that could have been avoided in the absence of marketing misconduct, some portion of the harm resulting from such shipments also could have been avoided had CSA registrants, such as defendant distributors, not acted improperly. I understand that all CSA registrants such as distributors of prescription opioids have legal obligations to monitor, identify and report shipments to regulatory authorities that may be unrelated to medical need and to prevent such shipments. The alleged failure to carry out these responsibilities thus contributed to the explosion of prescription opioid shipments that contributed to the opioid crisis documented by Prof. Gruber.

3. The estimates of the share of harms due to defendants' misconduct for Cuyahoga and Summit Counties reported in Tables III.16A-B do not attempt to uniquely attribute harm resulting from actions by any individual type of defendant. This does not reflect a problem with the underlying data or analysis but instead is the result of the fact that multiple parties are responsible for harms. For example, assume

[1] Cuyahoga Complaint, ¶3; Summit Complaint ¶3.
[2] Cuyahoga Complaint, ¶14; Summit Complaint, ¶14.

that 80% of harm can be attributed to manufacturer misconduct and 70% of that harm could have been avoided if distributors had acted properly. As an economic matter, manufacturers are appropriately held liable for at least the 10% of the harm that distributors could not have avoided. However, as discussed in the report, there is no unique or economically "correct" allocation of liability for the 70% of harm that could have avoided if each party had it met its legal obligations. Note that it is not necessarily the case that harm due to misconduct by CSA registrants is a subset of harm due to misleading marketing. Even in the absence of improper marketing, the failure of distributors and other CSA registrants to identify suspicious and excessive shipments can result in harm.

4. Nonetheless, the share of harm for which distributors can potentially be said to be liable can be estimated based on a variant of the framework used in Section VII. Specifically, the share of harm potentially attributable to distributors can be calculated by applying an estimate of the *share of excessive shipments that distributors failed to identify* (to the extent such a measure is available) instead of the estimate of the *share of shipments due to misleading marketing misconduct* in the Section VII framework. More specifically, the share of harm attributable to distributor misconduct can be measured as:

$$\begin{aligned} &Share\ of\ Harms\ Attributable\ to\ \textbf{Distributor}\ Misconduct \\ &= \ Share\ of\ Harms\ Attributable\ to\ Opioids \\ &\quad x\ Share\ of\ Opioid\ Harms\ Attributable\ to\ Opioid\ Shipments \\ &\quad x\ Share\ of Opioid\ Shipments\ Due\ to\ \textbf{Distributor}\ Misconduct \end{aligned}$$

5. That is, modifying the Section VII framework to address distributor misconduct requires only a modification of the last input, the "*Share of Opioid Shipments Due to Distributor Misconduct*," as the other two inputs are not specific to the attribution across the conduct of the multiple parties. This appendix presents an example of how this analysis can be applied if appropriate data become available

to estimate the share of prescription opioid shipments that reflect distributor misconduct. This example can be readily updated when appropriate estimates become available.

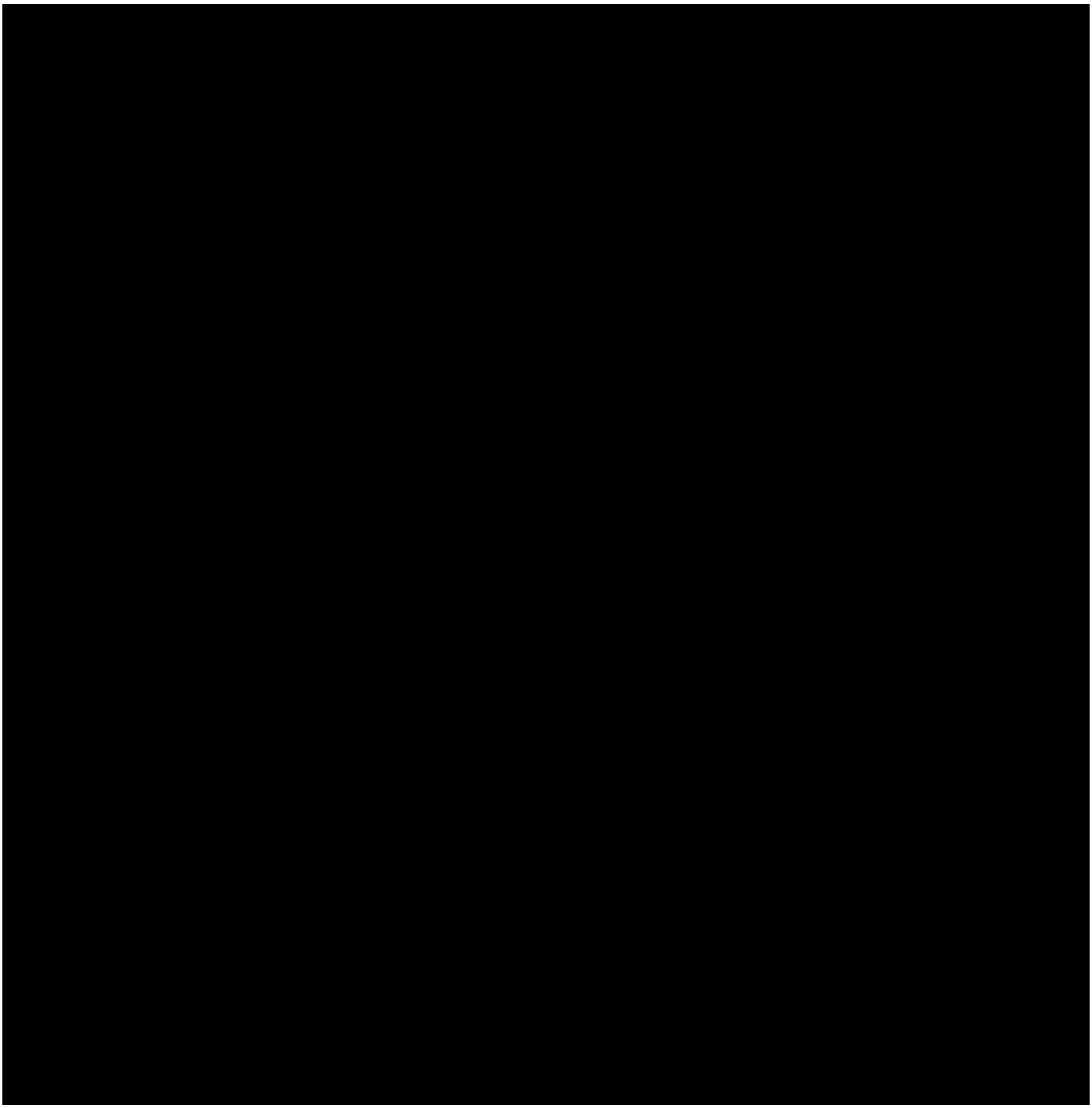
6. Table J.1 reports the data on the share of shipments for which the distributors are liable that have been provided to me by counsel and that I understand will be set forth in reports disclosed on April 15, 2019.

Table J.1: Percent of Shipments Attributable to Distributors' Misconduct

Year	Percent of Shipments Attributable to Distributors' Misconduct
1997	49.9%
1998	67.0%
1999	64.4%
2000	64.7%
2001	63.0%
2002	59.8%
2003	67.3%
2004	64.5%
2005	72.2%
2006	73.1%
2007	76.4%
2008	78.4%
2009	78.7%
2010	79.2%
2011	80.0%
2012	82.5%
2013	81.7%
2014	82.7%
2015	83.4%
2016	83.5%

These shares provide estimates of shipments of prescription opioids that would have been avoided in the absence of distributors' misconduct and can be used to estimate average shipments but-for distributor misconduct. Incorporating these estimates into the Approach 1 and Approach 2 analyses

(discussed in Section VI) then yields an estimate of the share of harms attributable to distributors' misconduct. Specifically, the calculation yields estimate of the product of the "*Share of Opioid Harms Attributable to Opioid Shipments*" and "*Share of Opioid Shipments Due to Distributor Misconduct*" in the equation above. Tables J.2 and J.3 below present these results.



7. The final step in the estimation is to combine these estimates with the "Share of Harm Attributable to Opioids" for the divisions identified in Cuyahoga and Summit counties, as described in Section IV. Tables J.4 and J.5 below report these results.